



CANNON BUILDING
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**STATE OF DELAWARE
BOARD OF PHARMACY**

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, February 17, 2016 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Tejal Patel, PharmD, Professional Member
Bonnie Wallner, R.Ph., Professional Member
Kenneth Sellers, Public Member
Julia Wheatley, Public Member
Jay Galloway, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

Kimberly Robbins, R.Ph., Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Zhi Wei Mai
Craig Clarke
Jaime Frink
Suzanne Raab-Long
Brian Cristobal
Denise Allwood
Jen Raibley
Justin Coyle
Scott Samples
Ronald Sansone
Ayana Patel
Cheryl Heiks
Dot Hart
Kevin Musto

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:32 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel, to approve the meeting minutes for January 20, 2016 with corrections. The motion unanimously carried.

UNFINISHED BUSINESS

Review of Propose to Deny Applications

MEDISCA, Inc. - Proposed to Deny 1/20/16 – After discussion the Board tabled this issue until next month's meeting. They requested Ms. Mast obtain the most current inspection report for their review and consideration.

Statutory and Regulatory Discussion

Ongoing - Practitioner/Pharmacy Ownership – The Board again reviewed proposed draft statutory amendments related to 24 **Del.C.** §2523(7). Mr. Dryden reported that the issue of restricted practitioner pharmacy ownership had been addressed with the Boards of Medical Practice and Nursing years ago when this issue was first raised. Neither Board had concerns with such a restriction at that time. The Board of Pharmacy's concern is the practitioner that automatically fills the prescription at the time of the visit and has it prepared for the patient at the time of the discharge of the visit. This puts undue stress on the patient to automatically get the prescription from the practitioner. In some cases patients are not aware that they have a choice and can have their prescription filled at the pharmacy of their choice. Mr. Dryden provided a copy and review of NABP's "Survey of Pharmacy Law" as requested by the Board at the January Board meeting. Mr. Shanehsaz voiced concerns with practitioner ownership due to conflict of interest and the choice of the best medication for individual patient issues. Ms. Patel had specific concerns pertaining to urgent care facilities that currently are not required to hold any type of pharmacy license but can dispense medications to patients. Ms. Wallner reviewed a particular problem she had faced with brand name product prescribing. Ms. Esposito brought up the issue of multiple practitioners and multiple pharmacies being used along with practitioner dispensing which could cause concerns with not having an accurate patient profile and influencing good patient care and safety. Mr. Mangler expressed concerns with placing restrictions on practitioners precluding them from ownership of a pharmacy. He stated that federal law prohibits the practitioner from forcing the patient to utilize any specific pharmacy. Mr. Shanehsaz made a motion to table this issue until next meeting requesting Mr. Dryden to obtain information from both Maryland and Pennsylvania. Ms. Wheatley seconded the motion. Ms. Kelly asked that this item remain on the agenda for further discussion. The motion unanimously carried.

Ongoing - Provision for Disciplinary Action – Ms. Kelly and Mr. Dryden to discuss further, tabled until next meeting.

Ongoing - Clarification of 24 **Del. C.** §2512(e)(f), Inactive Status - bill preparation in process, tabled until the next meeting.

Ongoing - Patient Practitioner Relationship & E-Prescribing Update – Ms. Kelly stated the changes are provided for review. Ms. Kelly asked that this item remain on the agenda for further discussion.

Regulation 1.4 – Controlled Substance CE – Mr. Dryden provided the Board a copy of 24 **Del.C.** §2512 and current Pharmacy Regulation 1.4. The Board reviewed the proposed amendment to 1.4 to require 2 credits of Controlled substance study towards the 30 credit requirement biennially. A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve amendment as proposed. The motion unanimously carried.

16 **Del. C.** §4762 – Pharmacist Providing Syringes Without a Prescription – The Board reviewed correspondence from the Delaware Pharmacist's Society. The word "prescription" is an issue since some insulin does not require a prescription. The Board determined to refer this issue to the legislative Committee for further review.

PRESIDENT'S REPORT

No report.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0004897 Rekha Rao
A1-0004898 Deborah P. Hanson
A1-0004899 Falak A. Thaker
A1-0004900 Zoya Shub
A1-0004901 Arin R. Passmore
A1-0004902 Ryan T. Albano
A1-0004903 Patricia A. Morris

Pharmacist Intern:

A7-0002411 Vivian N. Nkweteyim
A7-0002412 Julia E. Kaminski

A motion was made by Mr. Galloway and seconded by Ms. Patel to approve the ratification of the Pharmacist/Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001794 BeneVi Health LLC
A9-0001795 ProCare Pharmacy Care, LLC
A9-0001796 Home Towne Rx Dept
A9-0001797 RxC Acquisition Company
A9-0001798 AGH Rediscripts Pharmacy
A9-0001799 Forest Hill Pharmacy, LLC
A9-0001800 Emerald Pharmacy LLC
A9-0001801 Resource Pharmacy
A9-0001802 TMT Pharmaceutical Management dba Advanced Rx Pharmacy 031
A9-0001803 Factor One Source Pharmacy, LLC
A9-0001804 USRC Pharmacy, LLC
A9-0001805 Temple University Hospital Outpatient Pharmacy
A9-0001806 Trinity Medical Pharmacy
A9-0001807 AmendRx at Northern Pharmacy
A9-0001808 InnovaScript
A9-0001809 Northside Pharmacy Long Term Care
A9-0001810 ProCare Pharmacy Care, LLC

Wholesale Distributor Licensure Approval Ratifications

A4-0001721 BioRidge Pharma, LLC
A4-0002277 Omnicare Distribution Center, LLC
A4-0002278 ZO Skin Health, Inc.
A4-0002279 Med-Pro Distributors, LLC
A4-0002280 Trigen Laboratories, LLC
A4-0002282 PharMEDium Services, LLC
A4-0002283 Sunstar Americas, Inc.
A4-0002284 Dendreon Pharmaceuticals, Inc.

Medical Gas Dispensers

None

Retail Pharmacy Licensure Approval Ratification

A3-0000998 Kmart Operations LLC, Kmart Pharmacy #7725

A3-0000999 Atlantic Apothecary

Retail Pharmacy Temporary Licensure Approval Ratification None

Outsourcing Facility None

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the above noted Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Mr. Dryden conducted PIC interviews with the following Pharmacists In Charge:
Ronald Sansone, CVS Dover, DE
Zhiwei Mai, CVS Bear, DE

Board Review of Hearing Officer Recommendations

E. Cirillo, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

J. Cirillo, a motion to approve the Hearing Officer Recommendation as written was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Board Review of Consent Agreement

Olusegun Adediran – pharmacist - a motion to approve the Consent Agreement as written was made by Mr. Shanehsaz and seconded by Mr. Galloway. The motion unanimously carried.

Board Review of Facility Applications

PharMedium Services, TX - Outsourcing Facility, a motion to Propose to Deny the application was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion unanimously carried.

Absolute Veterinary Compounding Pharmacy - Non Resident - a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

Darjen Inc, - Non Resident - a motion to table the application was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

Owens & Minor Distribution, Inc. - Wholesale Distributor - a motion to approve the application was made by Mr. Galloway and seconded by Mr. Shanehsaz. The motion unanimously carried.

Expedien Rx Pharmacy - Non Resident - a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Patel. The motion unanimously carried.

Sentrix Pharmacy & Discount - Non Resident - a motion to approve the application was made by Mr. Shanehsaz and seconded by Ms. Wallner. The motion unanimously carried.

Board Review of Pharmacist Application

Clay Addison Parkel – Pharmacist - a motion to approve the application was made by Mr. Shanehsaz and seconded by Mr. Sellers. The motion unanimously carried.

Continuing Education Approval

The Drug Enforcement Administration (DEA) invited Delaware pharmacists to participate in an upcoming Pharmacy Diversion Awareness Conferences (PDACs) in Wilmington, DE. DEA is offering two regional one-day conferences, with one on Saturday, March 19, 2016, and another on Sunday, March 20, 2016. Each one-day conference is open to pharmacy personnel (pharmacists, pharmacy technicians, or loss-prevention

personnel) who are employed by pharmacies or hospitals/clinics that are registered with DEA in Delaware. The conference is designed to help pharmacy personnel identify and respond to potential diversion activity. Location details, a conference agenda, and a link to the online registration form are available on the [DEA website](#). There is no registration fee for these conferences. Upon completion of the one-day conference, pharmacists and pharmacy technicians may receive seven continuing pharmacy education hours (0.7 CEUs).

Pharmacist & Pharmacy - Discussion/Action Items

Christiana Hospital - DoseEdge Pharmacy Workflow Manager – Mr. Scott Samples provided the Board with a presentation of the DoseEdge system currently being used at the Christiana Hospital. Questions arose surrounding gowning, sterility, and pharmacist oversight and system documentation. The Board agreed with the system's attributes of better efficiency, safety and sterility.

Naloxone Standing Orders – Mr. Jamie Mack (DPR) and Mr. Justin Coil (Walgreen's DM) provided the Board with information of current statutory status of Naloxone. Walgreen's legal department had some concerns with current statutory language and liability issues that may arise. Walgreen's is currently making Naloxone available in 39 states. The Board was very vocal on their positive support of the Naloxone initiative.

3PL-Licensure Discussion – This issue was tabled until the next meeting.

Parata Automation Procedures – Mr. Kevin Musto and Mr. Brian Cristobal provided the Board with a presentation of the Parata Automation process. The Parata packages multiple medications meeting USP/NF requirements for labeling and packaging. The Board had concerns with multiple medications in one package; changing medication orders and their effect on packaging and child safety requirements. Mr. Musto wanted to have Board approval for the Parata packaging system; for the use of controlled substances in the package which is currently prohibited under Regulation; and wanted to perform a final check on only 10% of the prescriptions processed. After much discussion, Mr. Shanehsaz made a motion to approve the Parata system for packaging multiple medications but not with controlled substances being mixed with non-controlled substances and requiring 100% final check of all prescriptions filled. Mr. Sellers seconded the motion. Ms. Wallner, Ms. Esposito, and Ms. Patel were in favor of the motion. Ms. Wheatley and Mr. Galloway were not in favor of the motion. The motion carried.

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

CHPA - draft Model State Dextromethorphan Legislation - The Board reviewed the draft Model State Dextromethorphan legislation. The Board had concerns with the penalties proposed, the effect of this legislation on patients over the age of 18 and whether the abuse of Dextromethorphan was an actual concern that has been seen in Delaware to warrant this restriction. Ms. Wallner made a motion not to support this proposal, seconded by Mr. Shanehsaz. The motion unanimously carried. The Board requested to refer this issue to the legislative Committee for further review along with the syringe issue raised above.

Continuing Education – Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

No Report

Controlled Substance Liaisons – Tejal Patel, Hooshang Shanehsaz, Jay Galloway and David Dryden:

No Report

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden made available to the Board the documents from the Annual FDA meeting held in November 2015 related to compounding.

Mr. Dryden reported that at the request of NABP he had attended and chaired the NABP Law enforcement Committee. He briefly discussed the DEA CE meeting and recommended the Board members attend the meeting if their schedules permitted. He stated that the Office is inspecting veterinarians that are controlled substance dispensers. Ms. McCreary reported that for January she had 4 pre-inspections, 5 new ownership inspections, 8 routine inspections, 1 retail opening inspection, 2 remodeling inspection, 4 case complaint reviews, and 1 Drug Diversion Unit, inspection.

BOARD CORRESPONDENCE

Letter received from International Academy of Compounding Pharmacists.

Letter received from NABP - Compounding for Office Use.

NEWSLETTER UPDATES

The Board was provided an electronic copy of February 2016 published newsletter. The Newsletter addressed Naloxone, continuing education requirements, the PIC self-inspection report and the Delaware Professionals' Health Monitoring program as requested previously by the Board.

OTHER BUSINESS BEFORE THE BOARD

None.

PUBLIC COMMENT

No comment

NEXT SCHEDULED MEETING

The next meeting is scheduled for March 16, 2016 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Mr. Shanehsaz, and seconded by Ms. Patel at 12:50 pm. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy